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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,843	03/30/2001	Samir Kumar Brahmachari	Q63915	7045

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EXAMINER	
SMITH, CAROLYN L	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/820,843	BRAHMACHARI ET AL.	
	Examiner	Art Unit	
	Carolyn L. Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-24,26-30,32 and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-24,26-30,32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments and remarks, filed 9/8/06, are acknowledged. Amended claims 20, 26-30, and 32-33 are acknowledged.

Applicant's arguments, filed 9/8/06, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 20-24, 26-30, and 32-33 are herein under examination.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 20-24, 26-30, and 32-33 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Under the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (published in the O.G. notice (1300 OG 142) on 11/22/2005) a method that does not result in a physical transformation of matter MAY be statutory where it recites a concrete, tangible and useful result; i.e. a practical application. The "validating" step in instant claims 20, 30, 32, and 33 read in light of the specification is a computational step that is not

limited to be a physical step, so there is not recited physical transformation of matter. Nor do the claims recite a tangible result. In conclusion, these claims do not actually recite a physical transformation result or a concrete, TANGIBLE, and useful result. Therefore, they are considered to be non-statutory subject matter. Adding a step of displaying results of the identified outlier protein sequences would nullify this rejection. This rejection is maintained.

Applicants argue that the Examiner provides no analysis or reasoning as to why the claimed method does not produce a concrete, tangible, and useful result. As explained in the previous office action, the "validating" step as stated in the specification only refers to computational validation (see pages 8 and 14 of the specification). Therefore, "validating" read in light of the specification does not include any physical transformation of matter since everything appears to be taking place in the computer. While the result may be concrete and useful, the result is not TANGIBLE. The computational validating step of claim 20 is interpreted to also take place in the computer and is not presented in a tangible form, such as outputting or displaying the result to the user. Because there is a lack of a recited physical transformation of matter (all steps take place on the computer) as well as a lack of a concrete, tangible, AND useful result, the claims are considered to be nonstatutory subject matter. It is reiterated that adding a step of displaying results of the identified outlier protein sequences would nullify this rejection.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-24, 26-30, and 32-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

NEW MATTER

Claims 30, 32, and 33 recite "wherein the outlier protein selected in step (e) is validated as an anti-infective by testing said outlier protein as a diagnostic target", "wherein the outlier protein selected in step (e) is validated as an anti-infective by testing said outlier protein as a drug target", and "wherein the outlier protein selected in step (e) is validated as an anti-infective by testing said outlier protein as a vaccine candidate" which do not have adequate written description for the full breadth of these limitations. The specification only recites "validating computationally" (see page 8 (line 17) and page 14 (line 1)). One skilled in the art would consider validating diagnostic targets, drug targets, and vaccine candidates (as now stated in amended claims 30, 32, and 33) to encompass some sort of experimental laboratory work that is not supported in the specification. It is noted that further testing (specification, page 7, first paragraph) and validation are not the same thing. Because the full breadth of the limitations "wherein the outlier protein selected in step (e) is validated as an anti-infective by testing said

outlier protein as a diagnostic target", "wherein the outlier protein selected in step (e) is validated as an anti-infective by testing said outlier protein as a drug target", and "wherein the outlier protein selected in step (e) is validated as an anti-infective by testing said outlier protein as a vaccine candidate" do not appear to have adequate written support in the specification, claims, and/or drawings, as originally filed, these phrases are considered to be NEW MATTER. This rejection is necessitated by amendment.

Claim Rejections – 35 U.S.C. 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of the skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

LACK OF ENABLEMENT

Claims 20-24, 26-30, and 32-33 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed invention. This rejection is necessitated by amendment.

Claim 20 begins with calculating protein-sequence based attributes from protein sequences of a pathogenic organism (step a), clustering said protein sequences from this particular pathogenic organism (step b), identifying outliers from this particular pathogenic organism (step c), and then comparing the outliers with protein sequences in databases "to identify outlier proteins that are unique to said pathogenic organisms" which lacks enablement. One skilled in the art would not know how to get from the first three steps which deal with a particular pathogenic organism and then compare its outlier sequences to general undefined databases to "identify outlier proteins that are unique to said pathogenic organism". Merely comparing sequences to any database would not necessarily lead one skilled in the art to determination that the outlier proteins are unique. For example, if one compared the sequences to a National Center for Biotechnology Information (NCBI) database and there are no identical matches, it could be that the sequence does exist in another pathogenic organism, but it hasn't been sequenced yet. It is possible that another pathogenic organism has the sequence but it is rarely expressed and various other scenarios. Or the unique outlier sequence may have matches to ESTs at any particular percent homology when in fact the sequence is truly unique to that particular pathogenic organism. One skilled in the art would need to know at what point something is unique to the organism as opposed to being unique to the genus.

Due to the large quantity of experimentation necessary to determine that the outlier proteins are truly unique to the pathogenic organism, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to the same, and the breadth of the claims which fail to recite how to scientifically conclude that the proteins are unique to the pathogenic organism, the specification fails to teach the skilled artisan how to use the claimed invention. Claims 21-24, 26-30, and 32-33 are also rejected due to their dependency from claim 20.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-24, 26-30, and 32-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20, step (a) recites "wherein said protein sequences are predicted from either whole genomic sequences, or from partial genomic sequences comprising at least one chromosome" which is vague and indefinite. It is unclear what comprises at least one chromosome. One skilled in the art would consider "partial genomic sequences comprising at least one chromosome" to be nonsensical. A chromosome may comprise whole genomic sequences or a partial genomic sequence, but not the other way around. It is unclear if Applicants intend to mean that the partial genomic sequences are selected from at least one

chromosome or some other scenario. Clarification of this issue via clearer claim wording is requested. Claims 21-24, 26-30 and 32-33 are also rejected due to their dependency from claim 20.

Claim 20 (lines 13 and 15) recite "outlier proteins" which is vague and indefinite. It is unclear if Applicants intend the limitation to mean physical proteins, protein sequences, protein sequence-based attributes, or some other scenario. For example, in step (d), it is unclear whether to compare "outlier proteins" with protein sequences if the "outlier proteins" are physical proteins. Usually one skilled in the art compares sequences to sequences in databases, not physical proteins to sequences in databases. Clarification of this issue via clearer claim wording is requested. Claims 21-24, 26-30 and 32-33 are also rejected due to their dependency from claim 20.

Claim 20 (last 3 lines) recites selecting step (e) for "further testing" and "validating the outlier protein selected in step (e) as an anti-infective, claim 30 recites "wherein the outlier protein selected in step (e) is validated as an anti-infective by testing said outlier protein as a diagnostic target", claim 32 recites "wherein the outlier protein selected in step (e) is validated as an anti-infective by testing said outlier protein as a drug target", and claim 33 recites "wherein the outlier protein selected in step (e) is validated as an anti-infective by testing said outlier protein as a vaccine candidate" which is vague and indefinite. It is unclear if the testing involved in the validation is intended to be actual physical laboratory testing or a computational validation. Clarification of this issue via clearer claim wording is requested. Claims 21-24 and 26-29 are also rejected due to their dependency from claim 20.

Claim 29 limits the method to be a computer-implemented one (i.e. performed by a computer system). However, it is unclear what limitation of the METHOD of claim 20 is intended by the recitation of certain structural elements. Clarification of this issue via clearer claim wording is requested.

Conclusion

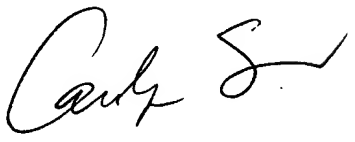
No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811.

November 9, 2006



Carolyn Smith
Examiner
AU 1631